

Claims

1. A method for detecting and/or screening and/or monitoring a cancer in an individual, said method comprising determining a first parameter represented by the concentration of TIMP-1 in at least one excreta from the individual, wherein the presence of the first parameter above a predetermined discrimination value is an indication that the individual has a high likelihood of either having a cancer or progression in a cancer.
2. A method according to claim 1 wherein the cancer is selected from the group comprising breast, prostate, colorectal, cervical, ovarian, lung, pancreatic, renal, vulvar, and hepatocellular carcinomas, minimal residual disease and recurrent cancer.
3. A method according to any of the preceding claims, wherein the excreta is saliva.
4. A method according to claim 1, 2 or 3, wherein the first parameter is the total concentration of TIMP-1.
5. A method according to claim 1, 2 or 3, wherein the first parameter is the combination of the concentration of total TIMP-1 and the concentration of free TIMP-1.
6. A method according to claim 5, wherein the combination is performed by logistic regression analysis.
7. A method according to any of the preceding claims, wherein the discrimination value is determined by determining the total concentration of TIMP-1 in the at least one excreta in both a healthy control population and a population with known cancer, thereby determining the discriminating value which identifies the cancer

population with a predetermined specificity or a predetermined sensitivity.

5 8. A method according to any of the preceding claims, wherein the method further comprises determining at least one second parameter representing the concentration of a marker for cancer different from any form of TIMP-1, in an excreta from an individual.

10 9. A method according to claim 8, wherein the first and second parameter are combined to result in a combined parameter wherein the presence of a concentration of the combined parameter above a predetermined discrimination value is an indication that the individual has a high
15 likelihood of having a cancer or there being a progression in a cancer.

20 10. A method according to claim 9, wherein the discrimination value is determined by determining the combined parameter in the at least one excreta in both a healthy control population and a population with known colorectal cancer, thereby determining the discriminating value which identifies the cancer
25 population with a predetermined specificity or a predetermined sensitivity.

11. A method according to claim 9 or 10, wherein the combination of the first and second parameter is performed by logistic regression analysis.

30 12. A method according to claim 8-11 wherein the at least one second parameter is the concentration of Carcino Embryonic Antigen (CEA).

13. A method according to any of the preceding claims, wherein the determination of the concentration is performed by means of an immunoassay or an active assay.

5 14. A method according to any of the preceding claims, wherein the immunoassay is an ELISA.

15. A method according to any of the preceding claims, wherein the active assay is zymography.

10 16. Use of a method according to claim 1-15, for detection of early stage cancer.

15 17. Use according to claim 16, for detection of early stage colorectal cancer.

18. Use according to claim 16, for detection of metastatic breast cancer.

20 19. Use of a method according to claim 1-15, for monitoring the response to cancer treatment.

25 20. Use of a method according to claim 1-15, for monitoring the recurrence of a cancer.

30 21. A dipstick for performing the method according to claim 1-15, wherein said dipstick comprises a first colour indication zone, comprising antibodies specific for TIMP-1.

35 22. A dipstick according to claim 21, wherein the first zone further comprises at least one reagent which can give an optically visible colour change in the zone dependent on the concentration of TIMP-1 in at least one excreta.

23. A dipstick according to claim 21 or 22, wherein the dipstick further comprises a second colour indication zone, able to react with at least one substance normally present in the excreta, and thereby providing an optically visible colour change in the zone for controlling that the stick is used properly.

24. A dipstick according to claim 21-23, wherein said dipstick further comprises a third colour indication zone, comprising antibodies specific for CEA.

25. A dipstick according to claim 21-24, wherein the first zone further comprises at least one reagent which can give an optically visible colour change in the zone dependent on the concentration of CEA in at least one excreta.